



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,226	11/19/2003	Ji-Young Kim	39894-00601	6919

29880 7590 05/03/2006

FOX ROTHSCHILD LLP
PRINCETON PIKE CORPORATE CENTER
997 LENOX DRIVE, BUILDING #3
LAWRENCEVILLE, NJ 08648

EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,226	Applicant(s) KIM ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 158-218 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 158-218 is/are rejected.
- 7) ☒ Claim(s) 165 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>A-C</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims

Claim Objections

Claim 165 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim repeats the limitation of sodium tripolyphosphate for the independent claim 158.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 203-204, 208-212, 214 and 217-218 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen (US 2002/0141950).

Chen teaches dental bleach compositions that are enamel safe. The compositions are placed on a strip to be delivered to the teeth (see figure 7), which encompasses claims. The compositions comprise a bleaching agent, which include hydrogen peroxide. They are included ranging from 0.5 to 25%. The thickener is

Art Unit: 1614

preferably polyvinyl pyrrolidone (PVP) and is incorporated ranging from 0.2 to 60%.

Polyvinyl pyrrolidone has the advantage of serving as a thickening agent or gelling agent while failing: to interfere with release of oxygen ions from the bleaching agent, chemically etching tooth enamel, remove calcium from the tooth and solidifying the dental bleach. The compositions also comprise a liquid component such as glycerin and propylene glycol, the plasticizers used in the instant claims 208-209 and 217-218. Water may also be a liquid component but is not necessary therefore making the compositions dry. The composition and the strip make a bilayer where the compositions are the adhesive layer and the strip is the backing layer, which encompasses the instant claims. In regards to claim 210, is inherent the PVP will form hydrogen bonds with peroxide because of their close proximity and interactions. In regards to claim 211, PVP is known to stabilize hydrogen peroxide in aqueous solutions, therefore it may be concluded PVP is a hydrogen peroxide stabilizer¹. Since the compositions of the reference are substantially the same as the compositions of the instant claims, compositions comprising hydrogen peroxide and polyvinyl pyrrolidone, the characteristics of the compositions of the reference such as adhesive strength upon hydration, should be substantially the same as the characteristics of the compositions, e.g. doubling of the adhesiveness of the patch, of the instant claims, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference anticipates the instant claims insofar as it teaches a dry patch comprising a hydrogen peroxide and polyvinyl pyrrolidone.

¹ Merianos et al. (US 5,130,124) see col. 2, lines 31-35.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 158-218 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sagel et al. (US 6,136,297) in view of Tapolsky et al. (US 6,159,498).

Sagel et al. teach delivery systems for an oral care substance using a strip of material. The strip of material acts as a protective barrier layer for the oral care substance (col. 4, lines 22-24). This barrier layer may be considered a backing layer, which encompasses claims 161, 163, 176, 178, 190, 192, and 214. The oral active agent comprises 0.01% to 40%, preferably 1 to 7% of the composition. The oral active agents used include hydrogen peroxide, which encompasses the instant claims. Anti-tartar agents, such as polyphosphate, which include sodium tripolyphosphate (col. 7,

Art Unit: 1614

lines 47-49), may also be included in the whitening compositions of the reference. The adhesive used in the compositions are incorporated in a concentration ranging from 0.1 to 15%. The composition may comprise additional adhesives such as polyvinylpyrrolidone and hydroxypropyl cellulose (col. 12, lines 53-68). If the gel is aqueous, water comprises 0.1 to 95% of the composition (col. 12, line 24). It can be concluded when water is 0.1%, the compositions qualify as a dry state and the term "if means there could also be 0% water added to the composition encompassing the instant claims. The compositions also comprise additional carriers such as glycerin and propylene glycol (col. 12, lines 64-65), which encompasses claims 166-167, 181-182, 196-197, 208-209 and 217-218. The adhesive gel composition on the strip creates a two-layer system, which encompasses claims 160, 175, 189 and 212. Buffers are incorporated to stabilize the compositions, keeping the pH preferably between 6 and 7, which encompasses claims 168, 183, 198 and 211 (col. 12, lines 30-32). Since the compositions of Sagel et al. are substantially the same as the compositions of the instant claims, compositions comprising hydrogen peroxide and polyvinyl pyrrolidone, the characteristics of the compositions of the combined references such as adhesive strength upon hydration and the ability of the compositions to leave less than 10% of the materials of the dry patch on a surface not treated, should be substantially the same as the characteristics of the compositions of the instant claims, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference differs from the instant claims insofar as it does not use polyvinyl pyrrolidone

Art Unit: 1614

and hydroxypropyl methyl cellulose as the primary gelling or adhesive agents on the taught strip.

Tapolsky et al. teach a water-soluble, bioerodable pharmaceutical device that adheres to mucosal surfaces. The device comprises an adhesive layer and a nonadhesive layer creating a bilayer system as recited in claims 160, 175, 189 and 212. The device of the present invention is made of water-soluble components and is bioerodable. The use of water-soluble components allows the device to dissolve over a period of time, with natural bodily fluids slowly dissolving and eroding away the carrier, while the pharmaceutical remains at the application site. Unlike bandages and other non-water-soluble film systems, the user of the present invention does not have to remove the device following treatment, does not experience the sensation of the presence of a foreign object at the mucosal surface or within the body cavity, given that upon application, water absorption softens the device, and over time, the device slowly dissolves or erodes away. The adhesive layer may comprise at least one film-forming water-soluble polymer, usually a cellulose derivative and at least one pharmacologically acceptable polymer known for its bioadhesive capabilities. The film forming polymer used includes hydroxyethyl cellulose and hydroxypropyl cellulose, preferably. The bioadhesive polymer of the adhesive layer includes sodium carboxymethyl cellulose (NaCMC) and polyvinylpyrrolidone (PVP), or combinations thereof. These bioadhesive polymers are preferred because they have good and instantaneous mucoadhesive properties in a dry, film state. It can be concluded they are ideal for a dry composition. PVP is incorporated into the compositions ranging from 0 to 10% by weight (table 1).

Art Unit: 1614

Preferred combinations of bioadhesive polymers include PAA and NaCMC, NaCMC and PVP, or PAA and PVP. The backing layer component may comprise hydroxypropyl methyl cellulose, hydroxyethyl cellulose or hydroxypropyl cellulose, which encompasses the instant claims. Plasticizers, flavoring and coloring agents, and preservatives may also be included in the pharmaceutical delivery device of the present invention in the adhesive layer, the backing layer, or both. Crosslinking agents known in the art are appropriate for use in the invention and may include propylene glycol and glycerol (cols. 3-6). The reference differs from the instant claims insofar as it does not teach using peroxide or sodium tripolyphosphate in the compositions.

It would have been obvious to one of ordinary skill in the art to have used the delivery system to deliver the active agents, tripolyphosphate and peroxide, of the primary reference motivated by the desire to make a whitening compositions that the user does not have to remove following treatment, does not experience the sensation of the presence of a foreign object at the mucosal surface or within the body cavity and over time will slowly dissolve or erode away, as disclosed by the secondary reference.

2) Claims 187-194, 196-202, 205-207 and 215-216 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen (US 2002/0141950) in view of Gallopo et al. (WO 95/17158).

The primary reference is discussed above. Chen teaches whitening compositions comprising hydrogen peroxide and polyvinyl pyrrolidone (PVP) delivered by a strip. The

Art Unit: 1614

reference differs from the instant claims insofar as it does not teach using sodium tripolyphosphate in the whitening compositions.

Gallopo et al. teach whitening compositions to remove stains using tripolyphosphate and optional a source of active oxygen. The tripolyphosphate is preferably sodium tripolyphosphate (page 3, lines 34-36), which encompasses the instant claims. The tripolyphosphates are capable of removing stains and inhibit build up of surface attached stains (page 3, lines 14-20). The composition may be dry or wet compositions. When peroxides are used, preferred peroxides include hydrogen peroxide (page 4, lines 21-22). Thickeners that may be used in the compositions include PVP. Since the compositions of the of Gallopo et al. are substantially the same as the compositions of the instant claims, compositions comprising hydrogen peroxide, sodium tripolyphosphate and polyvinyl pyrrolidone, the characteristics of the compositions of the reference such as adhesive strength upon hydration and the ability of the compositions to leave less than 10% of the materials of the dry patch on a surface not treated, should be substantially the same as the characteristics of the compositions of the instant claims, since the compositions of the reference and the compositions of the instant claims are substantially the same. The reference differs from the instant claims insofar as it does not teach the compositions being delivered to the oral cavity in a patch form.

It would have been obvious to one of ordinary skill in the art to have sodium tripolyphosphate to the peroxide containing system of the primary reference motivated by the desire to make a patch that was able to whiten teeth and remove stains as well as inhibit new stains from occurring as taught by the secondary reference.

Obvious-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 158-218 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-66 of copending Application No. 10/915283 in view of Tapolsky. The claims are coextensive because both sets of claims read on a whitening patch comprising hydrogen peroxide, polyvinyl pyrrolidone and sodium tripolyphosphate. The two sets of claims differ from one another insofar the instant claims use hydroxypropyl methyl cellulose and the copending claims use hydroxypropyl cellulose. The secondary reference teaches different types of celluloses combined with polyvinyl pyrrolidone make good bioadhesives.

It would be obvious to one of ordinary skill in the arts to have use hydroxypropyl methyl cellulose or hydroxypropyl cellulose in the composition of the instant claims motivated by the desire produce a whitening compositions that the user does not have to remove following treatment, does not experience the sensation of the presence of a foreign object at the mucosal surface or within the body cavity and over time will slowly dissolve or erode away, as disclosed by the secondary reference.

This is a provisional obviousness-type double patenting rejection.

2) Claims 158-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-17 of U.S. Patent No. 6,946,142 in view of Merianos et al. (US 5,130,124). Although the conflicting claims are not identical, they are not patentably distinct from each other because they coextensive because they both claim dry patches comprising a whitening agent, an adhesive and a polyphosphate in a multi-layer system. The claims differ from the instant claims insofar as some of the claims have a broader scope such as different whitening agents as oppose to hydrogen peroxide, different types of phosphates and different polymers as opposed to just polyvinyl pyrrolidone of the instant claims. Merianos et al. teach PVP stabilizes hydrogen peroxide.

It would have been obvious to one of ordinary skill in the art to used polyvinyl pyrrolidone in the compositions motivated by the desire to stabilize the hydrogen peroxide as disclosed by the secondary reference.

3) Claims 158-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,682,721 in view of Merianos et al. (US 5,130,124). Although the conflicting claims are not identical, they are not patentably distinct from each other because they coextensive because they both claim dry patches comprising a whitening agent, an adhesive and a polyphosphate in a multi-layer system. The claims differ from the instant claims insofar as some of the claims have a broader scope such as different whitening agents as oppose to hydrogen peroxide, different types of phosphates and different polymers as opposed to just polyvinyl pyrrolidone of the instant claims. Merianos et al. teach PVP stabilizes hydrogen peroxide.

It would have been obvious to one of ordinary skill in the art to used polyvinyl pyrrolidone in the compositions motivated by the desire to stabilize the hydrogen peroxide as disclosed by the secondary reference.

4) Claims 158-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-6, 9-12, 15, 17, 20-23 and 25 of U.S. Patent No. 6,780,401 in view of Merianos et al. (US 5,130,124). Although the conflicting claims are not identical, they are not patentably distinct from each other because they coextensive because they both claim dry patches comprising a whitening agent, an adhesive and a polyphosphate in a multi-layer system. The claims differ from the instant claims insofar as some of the claims have a broader scope such as different whitening agents as oppose to hydrogen peroxide, different types of phosphates and

Art Unit: 1614

different polymers as opposed to just polyvinyl pyrrolidone of the instant claims. Merianos et al. teach PVP stabilizes hydrogen peroxide.

It would have been obvious to one of ordinary skill in the art to used polyvinyl pyrrolidone in the compositions motivated by the desire to stabilize the hydrogen peroxide as disclosed by the secondary reference.

5) Claims 158-218 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 10-11, 13-15 and 19-20 of U.S. Patent No. 6,682,721 in view of Merianos et al. (US 5,130,124). Although the conflicting claims are not identical, they are not patentably distinct from each other because they coextensive because they both claim dry patches comprising a whitening agent, an adhesive and a polyphosphate in a multi-layer system. The claims differ from the instant claims insofar as some of the claims have a broader scope such as different whitening agents as oppose to hydrogen peroxide, different types of phosphates and different polymers as opposed to just polyvinyl pyrrolidone of the instant claims. Merianos et al. teach PVP stabilizes hydrogen peroxide.

It would have been obvious to one of ordinary skill in the art to used polyvinyl pyrrolidone in the compositions motivated by the desire to stabilize the hydrogen peroxide as disclosed by the secondary reference.

Claims 158-218 are rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

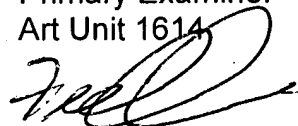
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Leah Roberts", with a long horizontal flourish extending to the right.

Frederick Krass
Primary Examiner
Art Unit 1614

A handwritten signature in black ink, appearing to read "Frederick Krass", with a large, stylized loop at the end.